AWARD NUMBER: W81XWH-12-1-0619

TITLE: Building a Family Systems Model to Promote Adherence to PTSD Treatment

PRINCIPAL INVESTIGATOR: Laura A. Meis, PhD

RECIPIENT: . Regents of the University of Minnesota

Minneapolis, MN 55455

REPORT DATE: October 2014

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command

Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;

Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE Form Approved OMB No. 0704-0188		GE Form Approved OMB No. 0704-0188
Public reporting burden for this collection of inf data needed, and completing and reviewing th this burden to Department of Defense, Washin 4302. Respondents should be aware that not	ormation is estimated to average 1 hour per response, inclu s collection of information. Send comments regarding this l gton Headquarters Services, Directorate for Information Op	ding the time for reviewing instructions, searching existing data sources, gathering and maintaining the nurden estimate or any other aspect of this collection of information, including suggestions for reducing erations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-ubject to any penalty for failing to comply with a collection of information if it does not display a currently
1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
October 2014	Annual	30 Sep 2013 - 29 Sep 2014
4. TITLE AND SUBTITLE		5a. CONTRACT NUMBER
Building a Family Systems i	Model to Promote Adherence to PTS	5b. GRANT NUMBER W81XWH-12-1-0619 5c. PROGRAM ELEMENT NUMBER
6. AUTHOR(S)		5d. PROJECT NUMBER
Laura A Meis		5e. TASK NUMBER
E-Mail: laura.meis@va.go	ov	5f. WORK UNIT NUMBER
7. PERFORMING ORGANIZATION	N NAME(S) AND ADDRESS(ES)	8. PERFORMING ORGANIZATION REPORT NUMBER
University of Minnesota 200 Oak Street SE, Suite 45 Minneapolis, MN 55455-207		
9. SPONSORING / MONITORING U.S. Army Medical Researc Fort Detrick, Maryland 2170		10. SPONSOR/MONITOR'S ACRONYM(S)
		11. SPONSOR/MONITOR'S REPORT NUMBER(S)
12. DISTRIBUTION / AVAILABILI Approved for Public Release		,
13. SUPPLEMENTARY NOTES		
out of treatment altogether. the most from these treatment treatment have yet to be estand after participation an Estaurveys is ongoing. We will their significant others, and the evidence-base for when outcomes. By studying Vete family-focused understandir fully recover. From these fin	One central and underutilized resolutions is Veterans' families, yet evident tablished. We will survey approximate for PTSD across three VAs (Minrothen conduct in-depth interviews witheir providers, to identify how to he, how, and why family involvement or rans and their families as they particularly of why some service members do dings, we will develop guidelines for	of for PTSD, only half of patients recover, and 1 in 5 will drop surce in keeping Veterans' in treatment and helping them to gain ce-based strategies for how to best utilize families in ately 378 Veterans and 185 of their significant others before eapolis, Palo Alto, and Phoenix). Data collection for these th Veterans who attended an EBT yet still suffer with PTSD, p Veterans get the most out of treatment. Findings will provide an improve adherence to EBTs for PTSD and treatment sipate in EBTs for PTSD, we will develop a comprehensive and not finish treatment and why those who do sometimes fail to providers, outlining how to involve the families in EBTs for providers and an emprove adherence to EBTs for PTSD.
IV. DODULOT ILIXINO		

17. LIMITATION OF ABSTRACT

18. NUMBER OF PAGES 19a. NAME OF RESPONSIBLE PERSON

USAMRMC

PTSD, couples, family, psychotherapy

16. SECURITY CLASSIFICATION OF:

a. REPORT b. ABSTI	C. THIS PAGE U	UU	17	19b. TELEPHONE NUMBER (include area code)
--------------------	----------------	----	----	-------------------------------------------

.

TABLE OF CONTENTS

	<u>!</u>	<u>Page No.</u>
1.	Introduction	5
2.	Keywords	5
3.	Accomplishments	5
4.	Impact	7
5.	Changes/Problems	9
6.	Products	11
7.	Participants & Other Collaborating Organizations	13
3.	Special Reporting Requirements	17
9	Annendices	17

1. INTRODUCTION: Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

Evidence-based psychotherapies (EBTs) for posttraumatic stress disorder (PTSD) result in clinically significant symptom relief for many patients and are recommended as first-line treatments by the VA/DOD Clinical Practice Guideline. Despite the success of these interventions, only half of patients receiving them can be expected to recover, and 1 in 5 will drop out of treatment altogether. One central and underutilized resource for maximizing treatment gains is family. PTSD has dramatic negative impacts on social and family relationships, and distress in these relationships predicts negative treatment outcomes. Veterans express strong interest in family-involved PTSD care and multiple organizations, including the VA and DoD, recommend prioritizing family involvement in the treatment of PTSD. Our long term objective is to build evidence-based strategies for how to involve families in EBTs for PTSD to improve treatment outcomes. In order to build these strategies, we must first observe service members and their families as they naturally participate in EBTs as delivered in real-world settings to identify when and how to intervene. The goal of this project is to develop a family-systems model for understanding adherence to EBTs for PTSD and to identify preliminary strategies for family involvement to improve treatment adherence and outcomes.

2. KEYWORDS: Provide a brief list of keywords (limit to 20 words).

PTSD, evidence based psychotherapy, family, psychotherapy adherence

3. ACCOMPLISHMENTS: The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction.

What were the major goals of the project?

List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

The major goals of the project include, 1) To determine the influence of family on treatment adherence among service members referred to EBTs for PTSD, 2) To evaluate a family-systems model of mechanisms of treatment adherence, 3) To obtain an in-depth understanding of the experiences of patients who adhere less to treatment through qualitative, open-ended interviews.

This report covers 9/30/13 through 9/29/14 (Months 13-24 in the statement of work). Below is a list of milestones and planned periods of completion for each milestone (in study months: "Mo.") and our progress towards those goals, as of this time.

- <u>Milestone 3:</u> Complete Time 1 Survey Data Collection for Objective 1 and 2; <u>Planned period of completion</u>: Mo. 12-26; We are 85.4% complete for Time 1 data collection (323 Veterans enrolled of the 378 target)
- <u>Milestone 4</u>: Complete Qualitative Interview Data Collection for Objective 3; <u>Planned period of completion</u>: Mo. 5-25; We are 63.0% complete for Veterans' interviews
- <u>Milestone 5:</u> Complete Time 2 Survey Data Collection for Objective 1 and 2; <u>Planned period of completion</u>: Mo. 7-29; We are 55.8% complete for Time 2 data collection (211 of 378 Time 2 surveys mailed)
- Milestone 6: Create Survey Data Set for Objective 1 and 2; Planned period of completion: Mo. 10-28
 - <u>Tasks during this reporting period</u>: Scanning data as it is obtained, writing computer syntax to score all measures; Status: Complete
- <u>Milestone 7</u>: Prepare Qualitative Interview Data for Analysis for Objective 3; <u>Planned period of completion</u>: Mo. 18-25; Transcription and de-identification of interview data is ongoing

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

The second year of the grant was largely devoted to data collection and monitoring response rates. We have completed the majority of Time 1 survey data collection, mailed approximately half of Time 2 surveys, and completed over half of our qualitative interviews. The specific objectives of this period are outlined above in the Milestones review. Each of the study Milestones and Tasks which were scheduled for completion during the period of this report were completed as scheduled, with the exception of recruitment targets for qualitative interviews. During the past year we identified that we were receiving poor rates of study referrals from one of our three sites. We requested a site addition once the problem was identified and this request was approved. The fourth site has been referring participants at rates consistent with those expected (26 per month).

Data collection is ongoing. Consequently, there are no significant results or key outcomes to report on at this time.

What opportunities for training and professional development has the project provided? If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

Nothing to Report.		

How were the results disseminated to communities of interest?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Nothing to Report.		
Nothing to Report.		

What do you plan to do during the next reporting period to accomplish the goals? If this is the final report, state "Nothing to Report."

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

Over the next year, we will complete data collection and data analysis. We will identify intervention targets for involving family in evidence based treatments for PTSD and develop guidelines for family-involvement in evidence based treatments for PTSD, based on data analysis and team feedback.

4. IMPACT: Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

What was the impact on the development of the principal discipline(s) of the project? If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Data collection is ongoing. Nothing to Report.

What was the impact on other disciplines?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Data collection is ongoing. Nothing to Report.

What was the impact on technology transfer?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- transfer of results to entities in government or industry;
- instances where the research has led to the initiation of a start-up company; or
- adoption of new practices.

Data collection is ongoing. Nothing to Report.

What was the impact on society beyond science and technology?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- improving public knowledge, attitudes, skills, and abilities;
- changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or
- improving social, economic, civic, or environmental conditions.

Data collection is ongoing. Nothing to Report.

5.	CHANGES/PROBLEMS: The Project Director/Principal Investigator (PD/PI) is reminded that
	the recipient organization is required to obtain prior written approval from the awarding agency
	Grants Officer whenever there are significant changes in the project or its direction. If not
	previously reported in writing, provide the following additional information or state, "Nothing to
	Report," if applicable:

Changes in approach and reasons for change

Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

Nothing	g to	Repo	rt.

Actual or anticipated problems or delays and actions or plans to resolve them

Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

As discussed above, we identified problems with the rate of referrals from a study site during the course of the past year. As a result, we requested a site addition and correspondingly revised our statement of work and diverted resources from the under-preforming site to the new site (site addition required no changes in expenditures except for transferring funds from the under-preforming site to the new site). Referral rates are now largely on track with our statement of work, with the exception of recruitment rates for qualitative interviews. In order for participants to be eligible for qualitative interviews, they must complete Time 1 and Time 2 surveys. Given the low rates of study referrals early in the course of survey recruitment, the pool of potentially eligible veterans for qualitative interviews is correspondingly smaller. As more veterans from Charleston complete Time 2 surveys, we anticipate the pool of eligible qualitative interviewees will improve. In order to allow for additional time to recruit Veterans, we anticipate recruiting Veterans through January 2015. This will still allow for the time necessary to complete data analysis on the qualitative interviews within the period of the grant.

We have also highlighted in prior quarterly reports that survey response rates are lower than expected (target was 70%; current response rate is 57%). With the increased rates of referral with our site addition (51.2 per month) and a 57% response rate, we expect to recruit 352 veterans by the end of the planned period for Time 1 data collection (93.1% of our goal). At that time, we will consult with our project statistician to determine if the Time 1 N as of that time is sufficient to test primary study hypotheses. If power analyses suggest data collection should continue, we will continue data collection until the target is reached, which we anticipate would take no more than an additional month.

Changes that had a significant impact on expenditures

Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

Nothing to Report.		

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

Nothing to Report.			
Significant changes in use or ca	re of vertebrate a	nimals.	
Not applicable.			
Significant changes in use of bio	ohazards and/or s	elect agents	
Not applicable.			

6.	PRODUCTS: List any products resulting from the project during the reporting period. there is nothing to report under a particular item, state "Nothing to Report."	If
•	Publications, conference papers, and presentations Report only the major publication(s) resulting from the work under this award.	

Journal publications. List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).

Data collection is ongoing	g. Nothing to Report.
issertation, abstract, or the eriodical or series. Include onference or in the report ne-time publication: Auth ibliographic information; tatus of publication (publis	lical, one-time publications. Report any book, monograph, we like published as or in a separate publication, rather than a le any significant publication in the proceedings of a one-time of a one-time study, commission, or the like. Identify for each or(s); title; editor; title of collection, if applicable; year; type of publication (e.g., book, thesis or dissertation); shed; accepted, awaiting publication; submitted, under ement of federal support (yes/no).
Data collection is ongoing	y. Nothing to Report.
resentation produced a ma	nuscript.
Data collection is ongoing	g. Nothing to Report.

Data collection is ongoing. Nothing to Report.	
Ident	nologies or techniques ify technologies or techniques that resulted from the research activities. In additio lescription of the technologies or techniques, describe how they will be shared.
Data	collection is ongoing. Nothing to Report.
Ident	ations, patent applications, and/or licenses ify inventions, patent applications with date, and/or licenses that have resulted from search. State whether an application is provisional or non-provisional and indicate pplication number. Submission of this information as part of an interim research
the ap	rmance progress report is not a substitute for any other invention reporting red under the terms and conditions of an award.

Other Products

Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment, and/or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

- data or databases;
- biospecimen collections;
- audio or video products;
- software;
- models;
- educational aids or curricula;
- instruments or equipment;
- research material (e.g., Germplasm; cell lines, DNA probes, animal models);
- *clinical interventions*;
- new business creation; and
- other.

Data collection is ongoing. Nothing to Report.								

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change."

Example:

Name: Mary Smith
Project Role: Graduate Student

Researcher Identifier (e.g. ORCID ID): 1234567

Nearest person month worked: 5

Contribution to Project: Ms. Smith has performed work in the area of

combined error-control and constrained coding.

Funding Support: The Ford Foundation (Complete only if the funding support is provided from other than this award).

Name: Laura Meis

Project Role: Principal Investigator

No change

Name: Afsoon Eftekhari

Project Role: Site Investigator (Palo Alto site)

No change

Name: Lee Kravetz

Project Role: Research Assistant (Palo Alto site)

Nearest person month worked: 4

Contribution to Project: Mr. Kravetz assisted with study activities at the Palo Alto site and performed administrative and study tasks, such as site IRB submissions, data pulls and data

entry.

Name: Karen Kattar

Project Role: Site Investigator (Phoenix site)

No change

Name: Rebecca Swain

Project Role: Research Assistant (Phoenix site)

No change

Name: Peter Tuerk

Project Role: Site Investigator (Charleston site)

Nearest person month worked: 1

Contribution to Project: Dr. Tuerk has managed project activities at Charleston site as well as

provided input and expertise on evidence based treatments for PTSD.

Name: Martina Radic

Project Role: Research Assistant (Charleston site)

Nearest person month worked: 4

Contribution to Project: Mr. Kravetz assisted with study activities at the Palo Alto site and performed administrative and study tasks, such as site IRB submissions, data pulls and data

entry.

Name: Tina Velasquez

Project Role: Project Coordinator Nearest person month worked: 12

Contribution to Project: Ms. Velasquez has managed and coordinated project activities across all sites and has performed such tasks liaison between staff at all sites and with respective companies, study administrative tasks, recruitment, project management, IRB, database management and design, data entry and verification, transcription, etc.

Funding Support: DoD

Name: Melissa Polusny

Project Role: Co-Investigator (MN site)

No change

Name: Christopher Erbes

Project Role: Co-Investigator (MN site)

No change

Name: Michele Spoont

Project Role: Co-Investigator (MN site) Nearest person month worked: 1 month

Contribution to Project: Dr. Spoont provided expertise in treatment adherence for veterans

with PTSD, survey methodology, and qualitative methods.

Funding Support: DoD

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Nothing to report.			

What other organizations were involved as partners?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:

Organization Name:

<u>Location of Organization: (if foreign location list country)</u>

<u>Partner's contribution to the project</u> (identify one or more)

- Financial support;
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- Facilities (e.g., project staff use the partner's facilities for project activities);
- Collaboration (e.g., partner's staff work with project staff on the project);
- Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and
- Other.

Organization Name: Minneapolis VA Health Care System

Location of Organization: Minneapolis, MN

<u>Partner's contribution to the project</u> (identify one or more)

- Study activities take place at the Minneapolis VA and Minneapolis investigators are located at the Minneapolis VA
- Facilities (e.g., project staff use the partner's facilities for project activities)

Organization Name: Phoenix VA

Location of Organization: Phoenix, AZ

Partner's contribution to the project (identify one or more)

- Study activities take place at the Phoenix VA and Phoenix investigators are located at the Phoenix VA
- Facilities (e.g., project staff use the partner's facilities for project activities)

Organization Name: Palo Alto VA

Location of Organization: Palo Alto, AZ

Partner's contribution to the project (identify one or more)

- Study activities take place at the Palo Alto VA and Palo Alto investigators are located at the Palo Alto VA
- Facilities (e.g., project staff use the partner's facilities for project activities)

Organization Name: Charleston VA

Location of Organization: Palo Alto, AZ

<u>Partner's contribution to the project</u> (identify one or more)

- Study activities take place at Charleston VA and investigators are located at the Palo Alto VA
- Facilities (e.g., project staff use the partner's facilities for project activities)

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: For collaborative awards, independent reports are required from BOTH the Initiating PI and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to https://ers.amedd.army.mil for each unique award.

QUAD CHARTS: If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.

9. APPENDICES: Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

None.